

September 25, 2001

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

11963

Dear Sir/Madam,

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, this is to notify you that we will be making the following statement of nutritional support on the professional sample package labeling (samples not for sale) for Slo-Niacin® (polygel® controlled-release niacin) dietary supplement.

• Your doctor gave you niacin to help maintain cholesterol levels already in the normal range.

Should you have any questions or comments, please contact me at (763) 258-5576.

Sincerely,

UPSHER-SMITH LABORATORIES, INC.

Kimberly Oakins

Regulatory Affairs Coordinator

978 0162 LET 8625

UPSHER-SMITH LABORATORIES, INC.

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